Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for INVEGA is 1,406 days. Of this time, 1,021 days occurred during the testing phase of the regulatory review period, while 385 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(i)) became effective*: February 14, 2003. The applicant claims February 13, 2003, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the original IND was withdrawn within 30 days of the submission date. The IND effective date was February 14, 2003, which was 30 days after FDA receipt of the request to reinstate the IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the act*: November 30, 2005. FDA has verified the applicant's claim that the new drug application (NDA) for INVEGA (NDA 21–999) was initially submitted on November 30, 2005.

3. *The date the application was approved*: December 19, 2006. FDA has verified the applicant's claim that NDA 21–999 was approved on December 19, 2006.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 896 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments and ask for a redetermination by July 14, 2008. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by November 10, 2008. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Division of Dockets Management. Three copies of any mailed information are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA through FDMS only.

Dated: April 28, 2008.

Jane A. Axelrad,

Associate Director for Policy, Center for Drug Evaluation and Research.

[FR Doc. E8–10685 Filed 5–13–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–E–0278] (formerly Docket No. 2007E–0143)

Determination of Regulatory Review Period for Purposes of Patent Extension; ZOLINZA

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for ZOLINZA and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Submit written comments and petitions to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov*.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6222, Silver Spring, MD 20993–0002, 301–796–3602.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the human drug product becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product ZOLINZA (vorinostat). ZOLINZA is indicated for the treatment of cutaneous manifestations in patients with cutaneous T-cell lymphoma who have progressive, persistent or recurrent disease on or following two systemic therapies. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for ZOLINZA (U.S. Patent No. RE38506 E) from Sloan-Kettering Institute for Cancer Research, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated May 16, 2007, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of ZOLINZA represented the first permitted commercial marketing or use of the product. Thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for ZOLINZA is 2,449 days. Of this time, 2,266 days occurred during the testing

phase of the regulatory review period, while 183 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(i)) became effective*: January 24, 2000. The applicant claims October 2, 1999, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was January 24, 2000, which was the date the IND was removed from clinical hold.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the act*: April 7, 2006. The applicant claims December 6, 2005, as the date the new drug application (NDA) for ZOLINZA (NDA 21–991) was initially submitted. However, FDA records indicate that NDA 21–991 was submitted in several modules under the fast track drug development program. It is FDA's position that the approval phase begins when the marketing application is complete for review. The final module of the NDA making it complete for review was submitted on April 7, 2006.

3. *The date the application was approved*: October 6, 2006. FDA has verified the applicant's claim that NDA 21–991 was approved on October 6, 2006.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,433 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments and ask for a redetermination by July 14, 2008. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by November 10, 2008. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Division of Dockets Management. Three copies of any mailed information are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA through FDMS only.

Dated: April 28, 2008.

Jane A. Axelrad,

Associate Director for Policy, Center for Drug Evaluation and Research.

[FR Doc. E8–10689 Filed 5–13–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Preference for Healthy Start Grantees

AGENCY: Health Resources and Services Administration (HRSA), HHS.

ACTION: General notice.

BACKGROUND: This notice supplements the 2007 HRSA announcement (HRSA 08–023/08–031) of the availability of fiscal year (FY) 2008 funding for new and competing continuation applications for Healthy Start. Healthy Start strengthens communities to effectively address the causes of infant mortality, low birth weight and other poor perinatal outcomes for women and infants. Recently, new guidance became available with regards to funding FY 2008 Healthy Start programs.

SUMMARY: The Conference Report (H.R. Rep. No. 110–107) accompanying the Consolidated Appropriations Act 2008 (Pub. L. 110–161), Division G—Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 2008, indicates concurrence with the Senate report language regarding the recompetition of Healthy Start programs. Following the Senate Committee's recommendation, the Health Resources and Services Administration (HRSA) will give funding preference during the FY 2008 competition to current Healthy Start grantees.

Senate Report 110–107 urges "HRSA to give preference to current and former grantees with expiring or recently expired project periods."

FOR FURTHER INFORMATION CONTACT: Maribeth Badura, Director, Division of Healthy Start and Perinatal Services, Maternal and Child Health Bureau, HRSA, Room 18–12, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857; telephone (301) 443–0543; e-mail *MBadura@hrsa.gov.*

Dated: May 2, 2008.

Dennis Williams,

Acting Administrator.

[FR Doc. E8–10684 Filed 5–13–08; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Fogarty International Center; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of the Fogarty International Center Advisory Board.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public in accordance with the provisions set forth in section 552b(c)(9)(B), Title 5 U.S.C., as amended. The grant applications and/or contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications and/or contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Fogarty International Center Advisory Board.

Date: May 19–20, 2008.

Closed: May 19, 2008, 1 p.m. to 3 p.m.

Agenda: To review and evaluate grant applications and/or proposals.

Place: National Institutes of Health, Lawton Chiles International House, Bethesda, MD 20892.

Closed: May 20, 2008, 8:30 a.m. to 10:30 a.m.

Agenda: To review and evaluate grant applications and/or proposals.